US ERA ARCHIVE DOCUMENT

6/14/96

MEMORANDUM

Subject: PP# 5F4545/FAP# 6H5737 - QUIZALOFOP ETHYL ESTER (ASSURE®) ON THE

FOLIAGE OF LEGUME VEGETABLES (EXCEPT SOYBEANS) CROP GROUP, CANOLA AND

CANOLA PROCESSED COMMODITIES.

Review of May 23, 1996, Amendment.

Chemical No. 128711

(No MRID #) (DP Barcode D226692)

From: Francis D. Griffith, Jr., Chemist

Chemistry Branch I - Tolerance Support

To: D. McCall, Acting Section Head

Risk Characterization and Analysis Branch

Thru: E. Zager, Acting Chief

Chemistry Branch I - Tolerance Support

INTRODUCTION

E.I. duPont de Nemours and Company, Agricultural Products, in a letter dated May 23, 1996, signed by T.E. Catika submitted an amendment deleting proposed uses for Assure® (quizalofop ethyl ester) from all crops except canola and proposed revised tolerances for only canola seed and canola meal. This amendment was submitted in response to deficiencies noted in our 21 Feb 96 review by F. Griffith (qv). Our conclusions and recommendation follow.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- NONE -

RECOMMENDATION

CBTS recommends for the requested permanent tolerances for the combined residues of the herbicide quizalofop-p ethyl ester and the acid, all expressed as quizalofop ethyl ester in or on canola seed 1 ppm, and the Section 701 MRL for canola meal at 1.5 ppm.

A DRES analysis may be initiated using the CBTS suggested revised total quizalofop ethyl ester tolerances on canola seed at 1 ppm and canola meal at 1.5 ppm. There is no anticipated concentration of quizalofop ethyl in canola oil. There is no anticipated change in the secondary tolerances for quizalofop-ethyl in meat, milk, poultry, and eggs from the use of the additional quizalofopethyl treated feedstuffs. The DRES analysis should use these values.

CONCLUSIONS

1. CBTS Conclusion on Directions for Use

CBTS reiterates the petitioner has proposed an adequate set of directions for use of quizalofop-ethyl ester, formulated as Assure®, in conjunction with an approved oil concentrate, or a non-ionic surfactant on canola and crambie.

2. CBTS Conclusion on the Residue Analytical Method

CBTS reiterates that the results of the successful TMV is not a prerequisite for a tolerance on canola and canola processing commodities as there is already an enforcement method in PAM-II.

3. CBTS Conclusion on Magnitude of the Residue - Crop Field Trials

The petitioner presented a revised section F proposing a quizalofop-ethyl ester tolerance on canola seed at 1 ppm. The petitioner withdrew the proposed quizalofop-ethyl ester tolerance for foliage of legume vegetables from this petition.

The deficiencies 8b, 8e, and 8f are resolved.

4. <u>CBTS Conclusion on Magnitude of the Residue - Processed Food/</u> Feed

The petitioner has conducted an adequate canola processing study using canola bearing detectable residues following a single 6X exaggerated application with a 45-day PHI. Total quizalofop residues were shown to concentrate only in canola meal. Residues declined in canola oil. The petitioner presented a revised Section F proposing a total quizalofop Section 701 Maximum Residue Limit (MRL) on canola meal at 1.5 ppm, and deleting the proposed total quizalofop ethyl tolerances for canola oil. Deficiency 9 is resolved.

DETAILED CONSIDERATIONS

DIRECTIONS FOR USE

CBTS reiterates the petitioner has proposed an adequate set of directions for use of quizalofop-ethyl ester, formulated as Assure[®], in conjunction with an approved oil concentrate, or a non-ionic surfactant on canola and crambie.

RESIDUE ANALYTICAL METHOD

CBTS reiterates that the revised residue analytical method for quizalofop-p and its acid metabolite as presented in PP# 3F4268; ie, LAN-1, has been submitted for a Tolerance Method Validation (TMV) in EPA laboratories. The Analytical Chemistry Branch (ACB) noted several deficiencies in the method (see memoranda by H. Hundley dated 1 July 95). The petitioner needs to respond to ACB's concerns with a revised method before we can get the TMV back on track. CBTS reiterates that the results of the successful TMV is not a prerequisite for a tolerance on canola and canola processing commodities. There is already an adequate enforcement method for quizalofop-ethyl ester in PAM-II.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

DEFICIENCIES

- 8b. CBTS concludes that quizalofop and its metabolites, all expressed as quizalofop-p ethyl ester, are not expected to exceed the proposed 2 ppm tolerance on canola when Assure® II plus the surfactant are used as directed. However, this tolerance is higher than necessary (see conclusion 8f below).
- 8f. Since CBTS recommends for tolerances no higher then necessary, the petitioner will need to submit a revised section F proposing total quizalofop-ethyl ester tolerances for canola at 1 ppm for 40 CFR §180.441(a) and for the foliage of legume vegetables subgroup foliage of legume vegetables (except soybeans) at 0.5 ppm for 40 CFR §180.441 (c).

PETITIONER'S RESPONSE

The petitioner presented a revised section F proposing a quizalofop-ethyl ester tolerance on canola seed at 1 ppm.

The petitioner withdrew the proposed quizalofop-ethyl ester tolerance for foliage of legume vegetables from this petition.

CBTS COMMENTS

The deficiencies are resolved.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

DEFICIENCY

The petitioner has conducted an adequate canola processing study using canola bearing detectable residues following a single 6X exaggerated application with a 45 day PHI. Total quizalofop residues were shown to concentrate only in canola meal. Residues declined in canola oil. In a revised Section F the petitioner will need to propose a total quizalofop-ethyl ester Section 701 Maximum Residue Limit (MRL) on canola meal at 1.5 ppm. The petitioner needs to

delete the proposed total quizalofop-ethyl ester tolerances for canola oil in the revised section F.

PETITIONER S RESPONSE

The petitioner presented a revised section F proposing a quizalofop-ethyl ester maximum residue limit on canola meal at 1.5 ppm.

The petitioner withdrew the proposed quizalofop-ethyl tolerance for canola oil.

CBTS COMMENTS

Deficiency 9 is resolved.

cc:R.F.Taylor[PM-19, HFB/RD]R.F., Circu, Reviewer(FDG), PP#5F4545.
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:6//96:edit:fdg:6/14/96.
RDI:TPT-1:6/13/96:BrSrSci:RALoranger:6/13/96:ActBrCh:EZager:6/14/96.